SMALL GRANT PROGRAM FOR THE NIAMS

Release Date: January 16, 1998

RFA: AR-98-002

P.T.

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Application Receipt Date: April 29, 1998

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is seeking small grant (R03) applications to stimulate and facilitate the entry of promising new investigators into targeted, high priority areas of NIAMS research. This one-time solicitation will provide support for pilot research that is likely to lead to a subsequent individual research project grant (R01).

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), Small Grant Program for the NIAMS, is related to the priority area of chronic diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-11474-0 or Summary Report: Stock No. 017-001-11473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators. Foreign organizations and institutions are not eligible. Participation in the program

by investigators at minority institutions is strongly encouraged. Pilot project grants awarded through this RFA may not be used to support thesis or dissertation research.

Former and current recipients of NIH small research grants (R03), Academic Research Enhancement Awards (AREA) (R15), Mentored Clinical Scientist Development Awards (K08), Mentored Research Scientist Development Awards (K01), Shannon Awards (R55), or Individual (F32) or Institutional (T32) National Research Service Award (NRSA) training support are eligible to apply for this Small Grant Program, dependent upon the status of other support for the project. Any current support by the F32 or T32 mechanisms must terminate before Small Grant support begins. The work proposed may not overlap significantly with the aims of currently supported projects in which the Principal Investigator has participated during the last five years. (Information on such projects is to be provided as part of the Principal Investigator's Biographical Sketch, as described below under Application Procedures.)

Current and previous recipients of NIH funding through Research Project Grants (R01) or FIRST (R29) awards are ineligible for this Small Grants Program. Principal Investigators of research subprojects of Research Program Projects (P01) and Centers (P50 and P60) and individuals who have received research support from the National Science Foundation (NSF) or Department of Veterans Affairs (VA) as Principal Investigators are also ineligible. Individuals whose sole previous support has been through pilot and feasibility studies may apply.

Investigators who have questions about eligibility should contact one of the program officials listed under INQUIRIES.

MECHANISM OF SUPPORT

Applicants may request up to $50,000 (direct costs) per year for up to three years through the small grant (R03) mechanism. It is anticipated that grants would be awarded no later than September 30, 1998. These awards are not renewable. Before completion of the R03, investigators are encouraged to seek continuing support for research through a research project grant (R01).

Replacement of the Principal Investigator on this award is not permitted.

FUNDS AVAILABLE

It is estimated that $1.0 million (total costs) will be available to support approximately 10 to 15 awards under this program. Awards are contingent on the availability of appropriated funds and on the receipt of sufficiently meritorious applications meeting the stated eligibility requirements.

RESEARCH OBJECTIVES

The Small Grant program is designed to facilitate the entry of promising new investigators into high priority areas identified by the NIAMS. Investigators may apply for a small grant to support research in one of the following general areas:

Angiogenesis

o Endothelial cell dysfunction leading to changes in adhesiveness or blood vessel tone; endothelial cell interactions with inflammatory cells and components of the extracellular matrix; phenotypic changes and biochemical mechanisms of endothelial cell response to inflammatory/immune-mediated tissue injury as they relate to the normal function and diseases of connective tissue.

o Regulatory factors controlling vascular structure, including molecular events that regulate angiogenesis, endothelial and vascular smooth muscle cell growth and cell death in the context of rheumatic and other connective tissue diseases.

o Immune responses directed against vascular components

o Pathogenesis of vascular manifestations of rheumatic and systemic autoimmune diseases such as lupus, dermatomyositis, scleroderma and rheumatoid arthritis

o Studies of vasculitis and vasculopathies in animal models of rheumatic diseases, with emphasis on identification of pathogenetic mechanisms and molecular targets for therapeutic intervention

o Therapeutic potential of angiogenesis inhibitors/modulators in rheumatoid arthritis

o Therapeutic potential of angiogenesis inhibitors/modulators in psoriasis, immune and non-immune inflammation of the skin (including irritant and allergic contact dermatitis), autoimmune diseases of skin, atopic dermatitis, and wound healing

o Inflammatory cell interactions with vasculature in the initiation of immune and non-immune inflammation of the skin and in wound healing

o Mechanisms of exercise-induced changes in vascularization of muscle, bone, and connective tissue

o Mechanisms of vascularization of new tissue during wound healing in skin and muscle.

Mechanisms of self-recognition in autoimmunity

o Molecular pathways and regulatory steps in self-antigen processing

o Physicochemical properties of the complex between self-components and antigen-presenting molecules

o Design of therapies to prevent abnormal responses to self by affecting antigen processing

Stem Cell Biology

o Identification, isolation, and culture of stem cells of epidermis and skin appendages, as they relate to skin diseases and wound healing, and to the development of skin-based gene therapy for skin and systemic diseases

o Characterization of the mesenchymal progenitors of chondrocytes and osteoblasts, including factors that influence commitment to a particular differentiative pathway, and the ability of the cells to circulate and/or "home" to specific tissues

o Characterization of the satellite cells of muscle, including their derivation, location, relative numbers and relation to other stem cell types

Growth and Repair of bone and connective tissue, including cartilage, tendon, ligament and muscle

o Determination and regulation of the osteoblastic and osteoclastic lineages, including the characterization of precursor cells and key gene products, interactions with other cells of the marrow microenvironment, and the role of apoptosis

o Organization and function of the growth plate, including the differentiation of growth plate chondrocytes and the regulation of chondrocyte proliferation and hypertrophy

o Mechanisms of bone and connective tissue responses to anabolic stimuli such as mechanical loading and intermittent PTH

o Interactions of bone and connective tissue with materials of orthopedic instruments, implants and prostheses, including the induction of local osteolysis, and the enhancement of integration with bone

o Response of bone and connective tissue to injury, including fracture healing, repair of defects resulting from surgery, and repair of injuries to growth plate, tendon and ligament

o Molecular regulation of chondrogenesis, differentiation or articular chondrocytes, methodologies of chondrocyte culture, regulation of cartilage matrix assembly

o Elucidation of biomechanical signal transduction pathways in chondrocytes, studies on biomechanical regulation of the structure/function of the cartilage matrix, chondrocyte metabolic activities, responses to cytokines, gene expression

o Mechanisms of cartilage repair and regeneration, including chondroprogenitor cell biology, genetics, development of techniques for chondroprotection and repair of the articular surface, including gene therapy approaches

Models and Markers of gender and genetic factors in musculoskeletal injuries and diseases, including animal models of human disease

o Gender differences in risk factors for musculoskeletal injuries

o Analysis of genetic factors in the acquisition and/or loss of bone mineral density, bone quality, or fracture risk

Other Research

o Rheumatic and dermatological manifestations of acquired immunodeficiency syndrome

o Pathogenesis of alopecia areata and vitiligo.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on grant application form PHS 398 (rev. 5/95). Application kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, Email: asknih@od.nih.gov.

The following instructions are to be used in conjunction with the information accompanying application form PHS 398 (rev. 5/95). They refer only to selected items in the application form. All PHS 398 requirements must be adhered to, with the exception of those items affected by the following instructions; for example, the Research Plan is limited to 10 pages. Applications not conforming to the requested format will be returned to the applicant without review. Please note that some of the information to be omitted from the application at submission may be requested following review if the possibility of funding exists.

Face Page

o Item 2, Response to Specific Program Announcement: Check the box marked YES. Enter the RFA number (AR-98-002) and title (NIAMS Small Grants Program).

o Item 6, Dates of Proposed Period of Support. Up to a total of three years of support may be proposed.

o The RFA label available in the PHS 398 application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review.

Detailed Budget for Initial Budget Period (Page 4)

o Do not complete or submit this page.

Budget for Entire Proposed Period of Support (Page 5)

o Composite Budget Table: Enter total direct costs requested, up to a maximum of $50,000, for each year of support (up to three).

o Justification: Provide a narrative justification for each proposed personnel position, including role on the project and proposed level of effort

o Provide narrative justification for the additional resources requested for the conduct of the project.

Biographical Sketch (Page 6) (Complete for each of the key personnel listed on Form Page 2.)

o Research and Professional Experience: List current position(s) and those previous positions directly relevant to the application.

o List selected peer-reviewed publications directly relevant to the proposed project, with full citations.

o Provide information on research projects completed and/or research grants in which the investigator participated during the last five years which are relevant to the proposed project. For each project or grant listed, provide title, name of Principal Investigator, funding source, and role on project (if not Principal Investigator).

Other Support (Page 7)

o Do not complete or submit this section.

Research Plan

o Items a - d of the Research Plan (Specific Aims, Background and Significance, Preliminary Studies, and Research Design and Methods) may not exceed a total of 10 pages. Please note that a Progress Report is not needed; no competing continuation applications will be accepted for an R03.

Appendix

o Appendix material may not be used to circumvent the page limitations. Publications may not be submitted as appendix.

Checklist

o The Checklist should not be submitted.

Submit a signed original of the application and four signed copies in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC-7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, one additional copy of the application must be sent to:

Tommy L. Broadwater, Ph.D.
Scientific Review Branch
National Institute of Arthritis and Musculoskeletal and Skin
Diseases
45 Center Drive, Room 5AS-25U - MSC 6500
Bethesda, MD 20892-6500

In order not to delay review, it is important that applicants comply with this request.

Applications must be received by April 29, 1998. If an application is received after that date, it will be returned to the applicant without review. Only one Small Grant application may be submitted by a Principal Investigator. Applicants may not submit an R01 or any career award (K mechanism) application for the February 1 or March 1, 1998 receipt date if that application involves significant scientific overlap with a Small Grant application.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by CSR. Incomplete applications will be returned to the applicant without further consideration. NIAMS staff will review applications for responsiveness to the research objectives of this RFA and for the eligibility of the Principal Investigator under the requirements stated above. Applications found to be unresponsive or ineligible will be returned without further consideration.
Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review committee convened by the NIAMS in accordance with the usual NIH peer review procedures.

Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written review, comments on the following aspects of the application will be made in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in the assignment of the overall score.

(1) Significance

Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach
Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

(3) Innovation

Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) Investigator

Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment

Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition, the adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research will be reviewed. Plans for the recruitment and retention of subjects will also be evaluated.

The initial review group will also examine the provisions for the protection of human and animal subjects, the safety of the research environment, and conformance with the NIH Guidelines for the Inclusion of Women and Minorities as Subjects in Clinical Research.

AWARD CRITERIA

The following will be considered in making funding decisions:

- Quality of the proposed project as determined by peer review
- Importance of the area to NIAMS research
- Availability of funds.

INQUIRIES

Inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to one of the following persons, according to scientific area:

Rheumatic Diseases

Dr. Susana A. Serrate-Sztein
45 Center Drive, Room 5AS-37G
Bethesda, MD 20892-6500
Telephone: (301) 594-5032
FAX: (301) 480-4543
Email: SzteinS@ep.niams.nih.gov

Cartilage and Connective Tissue

Dr. Bernadette Tyree
45 Center Drive, Room 5AS-37J
Bethesda, MD 20892-6500
Telephone: (301) 594-5032
FAX: (301) 594-4543
Email: TyreeB@ep.niams.nih.gov

Muscle Biology

Dr. Richard W. Lymn
45 Center Drive, Room 5AS-49E
Bethesda, MD 20892-6500
Telephone: (301) 594-5128
FAX: (301) 480-4543
Email: LymnR@ep.niams.nih.gov

Orthopedics

Dr. James S. Panagis
45 Center Drive, Room 5AS-37K

Bethesda, MD 20892-6500
Telephone: (301) 594-5055
FAX: (301) 594-4543
Email: PanagisJ@ep.niams.nih.gov

Skin Diseases

Dr. Alan N. Moshell
45 Center Drive, Room 5AS-25L
Bethesda, MD 20892-6500
Telephone: (301) 594-5017
FAX: (301) 480-4543
Email: MoshellA@ep.niams.nih.gov

Bone Biology

Dr. William J. Sharrock
45 Center Drive, Room 5AS-37A
Bethesda, MD 20892-6500
Telephone: (301) 594-5055
FAX: (301) 480-4543
Email: SharrocW@ep.niams.nih.gov

Direct inquiries regarding fiscal matters to:

Sally A Nichols
Grants Management Office
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-49F, MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-3535
FAX: (301) 480-5450
Email: NicholsS@ep.niams.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410), as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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